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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,773	04/14/2005	Allen D. Delaney	SMAR-044	3141

24353 7590 08/08/2006

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,773	DELANEY, ALLEN D.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,12,15-17,28 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,7,12,15-17,28 and 43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION
Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, as specifically drawn to a method of screening for biologically active agents comprising combining a candidate biologically active agent with a specific polypeptide and determining the effect of said agent on phosphatase function.
(Upon election of group 1, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 2, claim(s) 1, as specifically drawn to a method of screening for biologically active agents comprising combining a candidate biologically active agent with a cell comprising a specific nucleic acid and determining the effect of said agent on phosphatase function.
(Upon election of group 2, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 3, claim(s) 1, as specifically drawn to a method of screening for biologically active agents comprising combining a candidate biologically active agent with a non-human transgenic animal model comprising a knockout of a specific gene and determining the effect of said agent on phosphatase function.
(Upon election of group 3, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 4, claim(s) 1, as specifically drawn to a method of screening for biologically active agents comprising combining a candidate biologically active agent with a non-human transgenic animal model comprising an exogenous and stably transmitted mammalian gene sequence and determining the effect of said agent on phosphatase function.
(Upon election of group 4, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 5, claim(s) 2, drawn to a method for diagnosis of cancer comprising determining the upregulation of expression in a specific polynucleotide.
(Upon election of group 5, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 6, claim(s) 7, drawn to a method of inhibiting growth of a cancer cell comprising downregulating a specific polypeptide.
(Upon election of group 6, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 7, claim(s) 12 and 15, as specifically drawn to a method of screening for targets of a cancer associated phosphatase, the method comprising comparing the pattern of gene expression in a normal cell and in a tumor cell characterized by upregulation of a particular gene.
(Upon election of group 7, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 8, claim(s) 12 and 15, as specifically drawn to a method of screening for targets of a cancer associated phosphatase, the method comprising comparing the pattern of protein phosphorylation in a normal cell and in a tumor cell characterized by upregulation of a particular gene.
(Upon election of group 8, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 9, claim(s) 16, drawn to an isolated nucleic acid.
(Upon election of group 9, Applicant must further select a single SEQ ID NO, as each SEQ ID NO represents a separate invention and not a species.)

Group 10, claim(s) 17, drawn to a method to treat a tumor comprising administer a compound of the general formula $\alpha(P_z)$.

Group 11, claim(s) 28, drawn to a compound for the treatment of a tumor of the general formula $\alpha(P_z)$.

Group 12, claim(s) 43, drawn to a method for visualizing a tumor in a patient comprising administering a compound of the general formula $\alpha(P_z)$I and visualizing the imaging moieties in the compound.

The inventions listed as groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: groups 1-12 encompass different special technical features as identified in the groupings above. The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because under unity of invention between different *categories* of inventions unity of invention will only be found to exist if specific combinations of inventions are present.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different

categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. The allowed combinations do not include multiple products (antibodies, nucleic acids, polypeptides), and multiple methods of using said products, as claimed in the instant application. The products themselves do not share significant structural elements to the extent that each member could be substituted, one for the other, with the expectation that the same intended results would be achieved. For example, the polynucleotide sequences comprise significant differences in chemical compositions and lengths which, in turn, encode a multitude of amino acids with different chemical compositions and lengths all of which would have different molecular weights, specificities, and biological activities. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application is considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group 1 is the main invention. After that, all other products and methods are broken out as separate groups (see 37 CFR 1.475(d).).

In the instant case, the first invention of the first category mentioned consists of a method of screening for biologically active agents comprising combining a candidate biologically active agent with a specific polypeptide and determining the effect of said agent on phosphatase function. It is noted that there is no recited "process of manufacture" of the specific polypeptides of group I and product claims are not drawn to the polypeptides recited in the method of group I. Therefore, a method of screening for biologically active agents comprising combining a candidate biologically active agent with a specific polypeptide and determining the effect of said agent on phosphatase function is considered the "main invention" and the remaining products and methods have been properly restricted into separate groups.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER